

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION**

UNITED STATES OF AMERICA <i>ex rel.</i>)	
BROOK JACKSON,)	
)	
Plaintiff,)	
)	Civil Action No.: 1:21-cv-00008-MJT
v.)	
)	
VENTAVIA RESEARCH GROUP, LLC;)	
PFIZER, INC.; ICON, PLC)	
)	
Defendants.)	
)	

PROTECTIVE ORDER

Pursuant to Rule 26(c) of the Federal Rules of Civil Procedure, and good cause appearing,

IT IS HEREBY ORDERED that a party or a non-party disclosing or producing information (including electronically stored information), documents, or things in this matter (“producing party”) may designate such information, documents, or things as Confidential under the following terms and conditions:

1. Any document, information, or thing may be designated Confidential if it is in good faith determined by the producing party to contain confidential or proprietary information, the unauthorized disclosure of which would result in competitive, commercial or financial harm to the producing party or its personnel, clients or customers, or information protected by HIPAA. Qualifying items include information in written, oral, electronic, graphic, pictorial, audiovisual, or other form, whether it is a document,¹ information contained in a document, item produced for

¹ The term “document” shall be synonymous in meaning and equal in scope to the usage of that term in Rule 34 of the Federal Rules of Civil Procedure, and shall include every writing and recording within the meaning given those terms in Rule 1001 of the Federal Rules of Evidence.

inspection, information revealed during a deposition, information revealed in an interrogatory answer, or otherwise.

2. A producing party may designate any document or other tangible information or thing as Confidential by stamping some conspicuous place thereof with the legend CONFIDENTIAL. For example, in the case of a document, a producing party may so mark the first page of a multipage document or each applicable page. In the case of other tangible items, a producing party may so mark any appropriate location. For example, in the case of a computer disk, a producing party may so mark the disk cover.

3. A non-producing party may also designate any document, information, or thing produced during the course of this proceeding, not already designated Confidential, as Confidential as if it were a producing party. The non-producing party shall accomplish such designation by notifying all parties in writing of the specific item so designated, within twenty business days of the production of such document, information, or thing, during which period said items shall be presumed Confidential. For documents, information, or things which were previously produced, the non-producing party shall have the opportunity to make such a designation within twenty business days of the entry of this Order.

4. A producing party may designate documents, information, or things disclosed at a deposition of a producing party or one of its present or former officers, directors, employees, agents, or independent experts retained for purposes of this proceeding as Confidential on the record during the deposition.

a. If a producing party designates such materials as Confidential on the record, the court reporter shall indicate on the cover page of the transcript that the transcript includes Confidential information, shall list the pages and lines numbers and/or exhibits of the transcript on

or in which such information is contained, and shall bind the transcript in separate portions containing Confidential and non-Confidential material. Further, during the period in which such Confidential information is discussed during the deposition, any person present during the deposition who is not a Qualified Person, as defined below, or the court reporter, shall be excluded from that portion of the deposition.

b. A non-producing party may designate documents, information, or things disclosed at a deposition as Confidential in the same manner as a producing party.

5. Should any party object to a designation of any information, documents, or things as Confidential or that are redacted pursuant to Paragraph 9, the parties shall attempt to resolve such objection in good faith on an expedited and informal basis. If the objection is not thereby resolved, the objecting party may apply for a ruling from the Court determining whether the materials in question are properly designated or redacted under the terms of this Protective Order. Until the Court makes such determination, all material designated as Confidential shall be treated as such.

6. All documents, information, or things designated as Confidential shall be made available only to the following Qualified Persons:

a. the parties to the proceeding, and the employees of the parties;

b. counsel of record in this proceeding, the employees of such counsel, outside vendors employed by such counsel for purposes of scanning, reproducing, or numbering documents, information, or things, and independent testifying or non-testifying experts or trial consultants retained by such counsel or by the parties in connection with this proceeding;

c. the person producing such materials;

d. the person who is the proprietor or source of such materials; and

e. the Court.

7. Materials designated as Confidential shall not be made available to persons other than those enumerated in paragraph 6 above, even if attached to or contained within otherwise non-Confidential materials, such as transcripts, memoranda, or affidavits; the Confidential information must be removed before the remaining materials may be made available to those other persons.

8. No information, documents, or things designated as Confidential shall be disclosed to testifying or non-testifying experts or consultants pursuant to the terms of paragraph 6 above unless and until such experts or consultants have first been supplied with and have read a copy of this Order and have executed an Acknowledgement in the form attached hereto as Exhibit 1. Where the expert or consultant is reasonably expected to testify at the trial of this matter, counsel for the party obtaining the Acknowledgement shall retain the original of the Acknowledgement and forward a copy to the opposing party's counsel within five business days of its execution. Where the expert or consultant will not testify at the trial of this matter, counsel obtaining the Acknowledgement shall retain the original, but no copy need be given to the opposing party's counsel.

9. In order to protect further against unauthorized disclosure of Confidential Information, and to comply with all applicable laws and regulations, the disclosing party may redact from produced documents, materials, or other things, or portions thereof:

a. Personally Identifying Information. The names, addresses, Social Security or tax identification numbers, and other personally identifying information of employees (other than employees' names), patients, health care providers, and individuals in clinical studies or adverse event reports whose identity is protected by law. However, other general identifying

information, such as patient or health care provider numbers, shall not be redacted unless required by federal law;

b. Protected Personal Data. Any personal data that is protected by any relevant federal, state or foreign data protection or privacy laws or regulations, including, without limitation, Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 (the “GDPR”), and the national laws implementing the GDPR; and

c. Trade Secrets. Trade secrets that include, but are not limited to, how a defendant manufactures its medications, including the percentage of ingredients in the medications; instructions for manufacturing the medications; the names of suppliers of products used in manufacturing the medications; batch sizes used to manufacture the medications; certificates of analysis or specifications; stability testing, protocols, and results; impurity testing, protocols, and results; and other commercially sensitive information.

10. Pursuant to 21 C.F.R. §§ 314.430(e) & (f) and 20.63(f), the names of any person or persons reporting adverse experiences of patients and the names of any patients that are not redacted pursuant to paragraph 9, shall be treated as confidential, regardless of whether the document containing such names is designated as Confidential Information. No such person shall be contacted, either directly or indirectly, based on the information so disclosed without the express written permission of the disclosing party.

11. Prior to filing with the Court or otherwise publicly disclosing any document or information designated as Confidential, the party seeking to file or otherwise disclose the Confidential document(s) or information shall contact opposing counsel. The party seeking to file or disclose the Confidential document(s) or information must specifically identify the Confidential document(s) or information to opposing counsel and counsel for the Parties must meet and confer

to attempt to resolve the issue of disclosure and confidentiality. If the Parties cannot agree as to the protection of the Confidential document(s) or information, the party seeking to prevent the filing or public disclosure of the document(s) or information shall seek a protective order from the Court and/or shall file a motion to seal with the Court. Any documents, information, or materials as to which a Confidential designation is disputed shall be treated as Confidential until and unless the Court rules otherwise.

In filing materials with the Court in pretrial proceedings, counsel shall comply with U. S. District Court L. R. CV-5(a)(7) and obtain a Court order prior to filing any documents under seal, and will file under seal only those specific documents and that deposition testimony designated Confidential, and only those specific portions of briefs, applications, and other documents that contain verbatim Confidential information, or that set forth the substance of such Confidential information in summary or analysis.

12. Nothing in this Order shall preclude any party to the proceeding or their attorneys from:

a. Showing materials designated as Confidential to an individual who either prepared or reviewed the document prior to the filing of this action, or is shown by the document to have received the document.

b. Disclosing or using, in any manner or for any purpose, any information, documents, or things from the party's own files.

c. Disclosing or using, in any manner or for any purpose, any information, documents, or things obtained from a source other than discovery or to which a party has a right of access independent of discovery.

d. Disclosing or using, in any manner or for any purpose, any information, document, or thing that is at the time of production or disclosure, or subsequently becomes, through no wrongful act or failure to act on the part of the receiving party, generally available to the relevant public through publication or otherwise, or is already rightfully in the possession of the receiving party at the time of production.

13. If either party is served with a subpoena or similar process, from any person or entity whatsoever, directing that party to produce any materials designated as Confidential not so designated by that party, counsel for that party shall within three business days give counsel for the designating party written notice of the fact of such service so that the designating party may seek a protective order or otherwise act to protect the confidentiality of the designated materials.

14. This stipulation shall not abridge any party's right to use any Confidential information at any trial concerning the merits of the party's disputes. The use of any Confidential information at any trial shall be governed by a pre-hearing order issued by the Court after consultation with counsel for all parties.

15. If a party discloses information subject to a claim of attorney-client privilege or attorney work product protection or some other legal privilege, protection, immunity or doctrine protecting information from disclosure, the disclosure of the information ("Protected Information") shall not constitute or be deemed a waiver or forfeiture of any claim of privilege or work product protection or any applicable state-law equivalent that the disclosing party would otherwise be entitled to assert with respect to the Protected Information and its subject matter. This provision is, and shall be construed as, an Order under Federal Rule of Evidence 502(d). Accordingly, as explicitly set forth in Rule 502(d), a party's production of Protected Information,

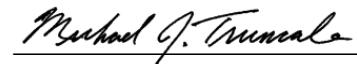
whether inadvertent or intentional, is not a waiver of any privilege or protection “in any other federal or state proceeding.”

16. In the event that Protected Information is inadvertently disclosed, such information may be retrieved by the disclosing party by giving written notice to the receiving party (which notice shall state the nature of the privilege or doctrine at issue, identify the document(s) by Bates number, and provide a description of the documents or information inadvertently disclosed). If a disclosing party notifies the receiving party of Protected Information, the receiving party shall promptly return or destroy all copies of such information and upon written request provide a certification of counsel that all inadvertently disclosed information has been returned or destroyed. After a disclosing party provides written notice of inadvertent production, a receiving party shall not copy, distribute, or otherwise use in any manner the disputed documents or information, and shall notify all persons to whom the receiving party has disseminated a copy of the documents or information that the documents or information are subject to this Order and may not be copied, distributed, or otherwise used pending further notice from the Court.

17. Within sixty days of the conclusion of this action, including any appeals, all originals and reproductions of any materials designated as Confidential shall be returned to the producing party or destroyed. However, counsel for the parties may retain one complete set of pleadings and motion papers filed with the Court, and one complete copy of deposition testimony given in this action (with accompanying exhibits). Counsel for the receiving party shall provide written verification to the producing party that all copies of such materials produced to the receiving party have been returned or destroyed, other than as indicated in this paragraph. Materials designated as Confidential that are in the custody of the Court are excepted from the terms of this paragraph.

18. The terms of this Order shall remain in effect after the action and any related appeals are concluded.

SIGNED this 9th day of June, 2022.



Michael J. Truncale
United States District Judge

Exhibit 1

**UNITED STATES DISTRICT COURT FOR
THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION**

UNITED STATES OF AMERICA <i>ex rel.</i>)	
BROOK JACKSON,)	
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Plaintiff,)	Civil Action No.: 1:21-cv-00008-MJT
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VENTAVIA RESEARCH GROUP, LLC;)	
PFIZER, INC.; ICON, PLC)	
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Defendants.)	

ACKNOWLEDGEMENT OF PROTECTIVE ORDER

I, _____, declare that:

1. My address is _____. My current employer is _____. My current occupation is _____.

2. I have received a copy of the Protective Order in this action. I have carefully read and understand the provisions of the Protective Order.

3. I will comply with all of the provisions of the Protective Order. I will hold in confidence, will not disclose to anyone not qualified under the Protective Order, and will use only for purposes of this action any confidential information that is disclosed to me.

4. Promptly upon termination of this action, I will return all confidential information that came into my possession, and all documents and things that I have prepared relating thereto,

to the outside attorneys for the party by whom I am employed or retained, or who noticed my deposition.

5. I hereby submit to the jurisdiction of this Court for the purpose of enforcement of the Protective Order in this action.

I declare under penalty of perjury that the foregoing is true and correct.

Name

Signature

Date